

DEPARTMENT OF HEALTH SERVICES

GENETIC DISEASE BRANCH
2151 BERKELEY WAY, ANNEX 4
BERKELEY, CA 94704



December 7, 2001

Dear Birth Attendants and Newborn Screening Providers:

The Department of Health Services is counting on your assistance in launching the Newborn Screening Tandem Mass Spectrometry (MS/MS) project on January 7, 2002. This is a large-scale research project that will provide supplemental screening for additional metabolic disorders in newborns. The result of the project is expected to lead to the expansion of the California Newborn Screening Program.

For the duration of the project, anticipated to be 12-18 months in length, parents' informed consent will be required to authorize their baby's already-collected newborn screening specimen to be used for additional testing via Tandem Mass Spectrometry (MS/MS). Parents will receive information about the supplemental screening project in the enclosed booklet. Please provide this booklet to your patients. Some patients may have questions for their health care providers to help them decide if they will participate in the study. For this reason, it is important that providers have an understanding of the project, its objectives, and how it can benefit newborns and their families.

Women who choose to deliver at home can participate in the supplemental screening research project if they give informed consent, document their consent by signature, and have the baby's blood specimen drawn by you between 12 hours and 6 days of age. You will not need to obtain additional blood for this project. The additional screening will be done on the same 5-spot filter paper specimen obtained for the mandatory screening. For the duration of the research, birth attendants will be responsible for ensuring information is provided to parents, informed consent is obtained and that the appropriate sticker denoting participation or refusal is affixed to both the demographic information and the filter paper portions of the newborn screening blood specimen collection form (refer to fact sheet). Most outpatient laboratories are not participating in the supplemental screening project. Therefore, your clients who have their newborn screening specimens collected at these sites will not be eligible to participate in the research project.

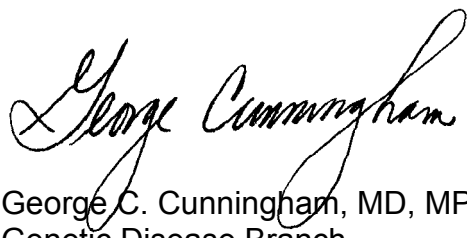
Enclosed you will find the following documents for your information and use in answering parents questions about this supplemental screening:

- 10 Copies of *Important Information for Parents about the Newborn Screening Test (IIP)* and a booklet reorder form. This booklet includes information about the current mandatory program as well as the supplemental screening research program in English and Spanish. Booklets translated into Chinese, Vietnamese, Cambodian, and Korean are also available.
- Fact Sheet for Prenatal Care Providers
- Suggestions for Prenatal Care Providers
- Informed Consent Protocol

We understand that the requirements of this research study represent an additional burden added to the routine newborn screening procedures. However, we are soliciting your cooperation and support because we are certain that they will result in a worthwhile prevention of heritable disease. We very much appreciate your assistance, which is essential to the success of the study. It is anticipated that at its conclusion, MS/MS will be incorporated into the regular Newborn Screening Program and the extra effort will no longer be required.

If you have questions about the program or would like additional information, please call the MS/MS Follow-up Coordinator at our toll-free number (866) 954-BABY (954-2229). If you prefer, you may e-mail your questions to msms@dhs.ca.gov. Thank you.

Sincerely,

A handwritten signature in black ink that reads "George Cunningham". The signature is written in a cursive, flowing style.

George C. Cunningham, MD, MPH, Chief
Genetic Disease Branch